Attorney Docket No.: 01.38

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Mammone, et al.	Group Art Unit: 1623
Serial No.:	09/925,333	Examiner: WHITE, Everett NMN
Filed:	August 9, 2001	

For: METHOD OF SKIN EXFOLIATION

APPELLANT'S BRIEF PURSUANT TO 37 CFR 41.31

Commissioner of Patents
Attention: Board of Patent Appeals and Interferences
Alexandria, VA 22313-1450

Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1, 4-7, 10-14, and 17-19 in the present application in the decision of April 25, 2006.

REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Color Access, Inc., the assignee of the application.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences relating to the instant application that would directly affect, be directly affected by, or have a bearing of any kind on the Board's decision in this appeal that are known to Appellants.

STATUS OF THE CLAIMS

Claims 1, 4-7, 10-14 and 17-19 remain rejected and pending in the application. Claims 2, 3, 8, 9, 15, 16 have been cancelled. The allowance of claims 1 and 4-6 (office action of August 29, 2005) has been withdrawn in the office action of April 25, 2006. The appealed claims are those of the Response under 37 C.F.R. 1.115, mailed on January 27, 2006, which were entered and considered.

STATUS OF AMENDMENTS

On September 19, 2006, following final rejection of April 25, 2006, Appellants submitted an amendment to claim 14 for consideration. The amendment was not entered and the accompanying arguments were deemed moot.

SUMMARY OF CLAIMED SUBJECT MATTER

The invention of independent claim 1 is a method of exfoliating the skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate (see page 2, lines 7-9, 20 and 21 of the specification).

The invention of independent claim 7 is a method for increasing levels of glycosaminoglycans in skin comprising applying to the skin in need of such increase a composition containing an effective amount of a mannose phosphate (see page 4, lines 21-23 of the specification).

The invention of independent claim 13 is a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin comprising applying to the skin afflicted with such a condition a composition containing an effective amount of a mannose phosphate (see page 5, lines 2-5 of the specification).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The outstanding issues are whether claims 1, and 4-6, drawing to a method of exfoliating the skin, are anticipated by U.S. Patent No. 5,520,926 (Ferguson, hereinafter referred to as "the reference"), whether claims 7 and 10-12, drawn to a method for increasing levels of glycosaminoglycans in skin, are anticipated by the reference, and whether claims 17-19, drawn to a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin, are anticipated by the reference.

The questions are whether the reference, which relates to a method of treating an organism with mannose-6- or 1-phosphate, to prevent or mitigate a fibrotic disorder, places within the possession of the skilled artisan, the methods of the present invention, including a method of exfoliation, comprising applying to the skin a composition containing an effective amount of a mannose phosphate; a method of increasing the level of glycosaminoglycans in the skin, comprising applying to the skin in need of such increase a composition containing an effective amount of a mannose phosphate; and a method of treating a condition associated with reduced levels of glycosaminoglycans in the skin, comprising applying to the skin afflicted with such a condition, a composition containing an effective amount of a mannose phosphate. More specifically, the questions are whether "photodamage' as defined in the reference is the equivalent of "photoaging" as used in the present specification, and whether the subject matter of claims 1 and 4-6 is inherently identical to the subject matter of claims 13 and 14 which allegedly rely on the same mechanism.

ARGUMENT

For purposes of determining patentability, claims 1 and 4-6 are grouped together, as they apply to the rejection based on 35 U.S.C. §102(b). Separately, claims 7, 10-14 and 17-19 are grouped together as they apply to the rejection based on 35 U.S.C. §102(b). The outstanding issues are whether the separate groups of claims are anticipated by the reference.

Rejection under 35 U.S.C. §102(b)

Claims 7, 10-14 and 17-19

Claims 7, 10-14 and 17-19 have been rejected under 35 USC §102(b) as being anticipated by the reference. It is the Examiner's position that the teaching in Ferguson of the use of mannose -6- and 1-phosphates to treat fibrotic disorders anticipates the present claims relating to the use of the same material to stimulate the production of glycosaminoglycans in skin, and to treat conditions associated with reduced levels of glycosaminoglycans, such as skin aging (chrono- or photo. The rejection, stated as follows, is repeated from the office action of August 29, 2005 (rejecting claims 7, 10-14 and 17-19):

> Applicants claim method for increasing levels of glycosaminoglycans in skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate. Additional limitations in the dependent claims include the mannose phosphate being mannose-6-phosphate, the use of a specific amount of mannose phosphate, and the method having specific skin conditions, which include dry skin, lines and wrinkles, and symptoms of chrono-and photoaging.
>
> The Ferguson patent discloses mannose 6- and 1-phosphates as being useful in the treatment of fibrotic disorders (see abstract). See column 4, lines 28-31, wherein the Ferguson patent discloses the invention thereof as being 'primarily of interest in relation to skin wounds, whether arising through surgery or other wise, including severe abrasions laceration and burns, but is also applicable to fibrotic disorders, which includes photo-damage.' See the examples disclosed in the Ferguson patent wherein the amounts of mannose phosphates used in the treatments are disclosed, which appear to be within the scope of the amounts of mannose phosphate set forth in the instant claims. The use of mannose phosphate to treat fibrotic disorders, which include and photo-damage, in the Ferguson patent anticipates the instantly claimed method

> of increasing levels of glycosaminoglycans in skin, since the instant claims disclose that photoaging of skin is a condition associated with reduced level of glycosaminoglycans in the skin (see instant Claim 14).

The Examiner states further in the office action of April 25, 2006:

> Also Applicants argument that there is a difference between the photo-damage skin of the Ferguson patent and the photo-aged skin of the instant claims is not persuasive. Hence Applicants arguments from a legal point of view is not persuasive.
>
> The mannose 6-phosphate applied to skin disclosed in the instant claims is identical to the mannose 6-phosphate applied to skin disclosed in the Ferguson patent. Applicants are reminded that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties Applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ 2d 1655, 1658 (Fed. Cir. 1990). See MPEP 21112.01.

The Examiner's position regarding "photo-aging" as the term is used in the art generally, and in the present specification specifically, and "photodamage" as it relates to the reference, is simply incorrect, both technically and legally.

To address the technical error first, equating photoaging with photodamage as these terms are used in the present specification and in the reference, respectively, is based on a misreading of each of the present specification and the reference. As stated in the reference, in column 4, lines 28-33:

> Although the invention is primarily of interest in relation to skin wounds, whether arising through surgery or otherwise, including severe abrasions lacerations and burns, it is also applicable to fibrotic skin disorders, e.g. *photo-damage (which is believed to up-regulate certain effectors of an increase in fibrous tissue)...*[emphasis added].

The fibrotic disorders referred to in the reference are characterized by an excess of fibrous material in the skin. An exemplary list of fibrotic diseases is found in column 1, lines 33-37 in the reference. Unlike the photo-damage disclosed in the reference, the present specification refers to photo-aging, which includes the symptoms of dry skin, lines and wrinkles. In fact, it is well-known to those skilled in the cosmetic arts as well as in photochemistry and photobiology, that "solar UV radiation damages human skin, affecting skin tone and resiliency, and leading to premature aging (i.e. photo-aging), the symptoms of which include leathery texture, wrinkles, mottled pigmentation, laxity and

sallowness", as stated in the attached abstract "Molecular mechanisms of photoaging in human skin in vivo and their prevention by all-trans retinoic acid", published in 1999, which abstract was previously submitted with the response mailed September 19, 2006, and the summary entitled "Aging – the skin", which was previously submitted with the response of January 27, 2006 (see Evidence Appendix). As indicated in the abstract, it has been proposed that photo-aging results from UV induction of enzymes which degrade skin collagen (i.e., fibrous material which keeps skin from sagging). Signs of aging skin, as set out in the summary, include wrinkles, sagging, and dryness.

Since "photodamage", as defined in the reference, and "photoaging", as used in the present specification and as understood by those skilled in the art, are mutually exclusive conditions, then, strictly from a technical point of view, there is no anticipation of the present claims by the Ferguson reference.

Similarly, from a legal point of view, the basis for rejection of the claims on the ground of anticipation also fails. Absence of a claim element from a prior art reference negates anticipation. *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.,* 224 USPQ 409 (Fed. Cir. 1984). The Appellants remind the Examiner that a composition comprising a mannose phosphate is not being claimed, and therefore *In re Spada* and MPEP 2112.01 have been misapplied to the present claims. The Appellants are instead claiming a method for increasing levels of glycosaminoglycans in skin, and a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin. The reference fails to disclose either a method for increasing levels of glycosaminoglycans in skin or a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin. Since the reference fails to disclose each and every element of the claimed inventions, there is no anticipation of the present claims by the reference.

Should the Examiner's basis of rejection be anticipation based on inherency, then this also fails. For the concept of inherency to apply in an anticipation rejection, the subject matter being claimed must undeniably and irrefutably flow from the prior art disclosure. *Hughes aircraft Co. v. United States*, 8 USPQ 2d 1580 (Ct. Cl. 1988). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstance is not sufficient. *In re*

Oelrich and Divigard, 212 USPQ 323 (CCPA) 1981). The skin to which a mannose phosphate would be applied according to the reference (skin exhibiting wounds or fibrotic disorders) is clearly not the same skin to which a mannose phosphate would be applied according to the methods of the present invention (dry and/or wrinkled skin associated with aging). Therefore, the result claimed in the present application would not "irrefutably flow" from the disclosure of the reference. Because the present invention addresses application of the mannose phosphate to a type of skin different from that disclosed in the reference, there can be no anticipation of the present claims by the reference. See *Perricone v. Medicis Pharmaceutical Corporation*, slip op. (CAFC, 05-1022-1023, December 2005).

The Appellants wish also to address the content of the Advisory Action of November 1, 2006. The Advisory Action indicates that the proposed amendment to claim 14 will not be entered because the amendment raises new issues that would require further consideration and/or search, the amendment is not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal, and the amendment presents additional claims without canceling a corresponding number of finally rejected claims. The Examiner comments as follows:

> The amendment filed September 19. 2006 also will not be enter because the metes and bounds of the phrase "other symptoms of chrono- and photoaging" cannot be determined which renders Claim 14 indefinite.

The Appellants cannot agree with the position taken by the Examiner. The amendment to claim 14 as discussed in the response of September 19, 2006, was presented to bring about conformity with the disclosure in the present specification at page 5, lines 2-5, and thereby to place the application in better form for appeal by simplifying the issue for appeal, i.e. whether "photoaging" as used in the present specification, is equivalent to "photodamage" defined in the reference. The amendment was presented to change "the" to "other" before "symptoms" to correct an apparent typographical error, thus making it clear that dry skin, lines and wrinkles are some of the symptoms of chrono- and photoaging – the symptoms with which the present invention is primarily concerned. As discussed above, the reference most specifically defines "photodamage" in column 4, lines 28-33, as effecting an increase in fibrous tissue manifested in fibrotic skin disorders, and provides an exemplary list of fibrotic diseases

in column 1, lines 33-37. On the other hand, the present specification addresses the symptoms of "photoaging", including dry skin, lines and wrinkles. By increasing the level of glycosaminoglycans in the skin, which help to retain moisture in the skin, the present invention relieves dryness and also plumps the skin to thereby reduce the appearance of lines and wrinkles and other symptoms of chrono- and photoaging (see page 2, lines 16-18, and page 4, line 28 – page 5, line 5). The amendment to claim 14, proposed in the previous response, was intended to make it clear that the aforementioned symptoms of dryness, lines and wrinkles are characteristic of photoaging and are not separate conditions therefrom. In view of this disclosure in the present specification, at page 5, lines 3-5, the amendment to claim 14 would require no further consideration and/or search. The claims must be definite when read in light of the specification. *In re Moore*, 169 USPQ 236 (CCPA 1971). Although the proposed amendment is fairly based on the application as filed, in further support of the Applicants' position, the response filed on September 19, 2006 included an abstract which discusses photoaging in human skin, more specifically, the symptoms of premature aging (also referred to in the abstract as photoaging) associated with solar UV radiation damage to the skin. The abstract provides a non-exhaustive list of five symptoms. The abstract is again presented herewith in the Evidence Appendix. It is well-established that a specification need not disclose, and in fact, preferably omits, that which is already known in the art. *Hybridtech Inc v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Circ. 1986). For these reasons, it is the Appellants position that claim 14, if amended to refer to "other symptoms of chrono- and photoaging", would be rendered indefinite.

The Appellants also wish to point out, in contrast to the reference in the Advisory Action, that no new claims have been presented. Therefore, no corresponding number of finally rejected claims was required.

In view of the technical and legal arguments presented above, it is clear that the rejection of claims 7, 10-14 and 17-19 as anticipated by the reference is improper and should be withdrawn.

Claims 1 and 4-6

Claims 1 and 4-6 also have been rejected under 35 USC §102(b) as being anticipated by the reference. It is the Examiner's position that the teaching in the

reference of the use of mannose -6- and 1-phosphates to treat fibrotic disorders anticipates the claims 1 and 4-6 relating to the use of the same material to exfoliate skin. The rejection, in the office action of April 25, 2006, is stated as follows:

> The method of exfoliating skin comprising applying to the skin a composition comprising mannose phosphate and the application of mannose phosphate for the treatment of photoaging skin are based on the same principle that involves removing the outmost layer of skin and replacing the outer layer with newly generated skin cells. Hence, upon further consideration, the subject of Claims 1 and 4-6 is inherently identical to the method of Claims 13 and 14 since the same mechanism used to carry out the subject matter of Claims 1 and 4-6 is identical to the mechanism used in Claims 13 and 14.

The Appellants cannot agree with the Examiner's reasoning for withdrawing the allowability of claims 1 and 4-6, drawn to a method of exfoliating the skin. The Examiner contends that if claims 7, 10-14, and 17-19 are not allowable for the reasons given, then claims 1 and 4-6 also are not allowable because the methods are inherently the same as the method of claims 7, 10-14, and 17-19. Nevertheless, the Appellants are not claiming a method of applying a mannose phosphate to the skin. The Appellants are claiming, in claim 1, a method of exfoliating the skin which supplements the natural sloughing process, and smoothes the surface texture of the skin, as measured by a reduction in flakiness. On the other hand, claim 13 is directed to a method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin. The enhanced synthesis of glycosaminoglycans results in increased water retention in the skin and skin plumping with a reduction in the appearance of lines and wrinkles. The respective populations of users of the two methods are not necessarily the same. The population of users having flakey skin in need of exfoliation will not necessarily be that population having dry, and/or wrinkled skin associated with aging. Young skin may exhibit flakiness, due, for example, to tanning, or the use of chemical peels and/or anti-acne agents. Dry skin, resulting from photo-aging, may not necessarily be flakey. Furthermore, the population of users having mature, photo-aged skin, and who are desirous of obtaining plumped skin which will reduce the appearance of dryness, lines and wrinkles, and sagging of the skin, will also not necessarily be the same population merely in need of exfoliation for treating flakey skin.

From a legal standpoint, there can be no anticipation of claims 1 and 4-6 by the reference. The Appellants are not claiming a composition comprising a mannose phosphate but a method of exfoliating the skin. The reference fails to teach either explicitly or implicitly a method of exfoliating the skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate. A method of exfoliating the skin (e.g. treating flakey skin) is not the same as the treatment of skin wounds or tissue exhibiting fibrotic disease. As the reference therefore fails to disclose each and every element of the claimed invention, there can be no anticipation of claims 1 and 4-6 by the reference. Because the present invention addresses the application of the mannose phosphate to a type of skin different from that disclosed in the reference, there also can be no implicit anticipation of claims 1 and 4-6 by the reference. The tissue to which a mannose phosphate would be applied according to the reference (skin exhibiting wounds or tissue exhibiting fibrotic disease) clearly is not necessarily the same skin in need of exfoliation. Therefore, the result claimed in the present application would not "irrefutably flow" from the disclosure in the reference.

In view of the arguments presented above, it is clear that the rejection of claims 1 and 4-6 as anticipated by the reference is improper and should be withdrawn.

CONCLUSION

In view of the arguments presented above, the rejection of claims 1, 4-7, 10-14 and 17-19, as anticipated by the reference, should be reversed as it is unfounded. The reference fails to teach any of the claimed methods, either explicitly or implicitly. The "photodamage" defined in the reference is not equivalent to the "photoaging" defined in the present specification, and the claimed method of exfoliation is not identical to the claimed method of increasing the level of glycosaminoglycans in skin. Moreover, the application of a mannose phosphate to skin wounds or to ameliorate the effects of fibrotic disorders resulting from photodamage would not necessarily anticipate the application of a mannose phosphate to flaky skin or to skin exhibiting the signs of photoaging. Accordingly the Appellants respectfully request that the Honorable Board reverse the decision of the Examiner finally rejecting the pending claims and declare that all pending claims in this application are allowable.

Respectfully submitted,

Date: November 13, 2006

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CLAIMS APPENDIX

1. A method of exfoliating the skin comprising applying to the skin a composition containing an effective amount of a mannose phosphate.

4. The method of claim 1 in which the mannose phosphate is mannose-6-phosphate.

5. The method of claim 1 in which the effective amount is from about 0.01 to about 10% by weight of the total composition.

6. The method of claim 1 in which the effective amount is from about 0.5 to about 3% by weight of the total composition.

7. A method for increasing levels of glycosaminoglycans in skin comprising applying to the skin in need of such increase a composition containing an effective amount of a mannose phosphate.

10. The method of claim 7 in which the mannose phosphate is mannose-6-phosphate.

11. The method of claim 7 in which the effective amount is from about 0.01 to about 10% by weight of the total composition.

12. The method of claim 7 in which the effective amount is from about 0.5 to about 3% by weight of the total composition.

13. A method of treating a skin condition associated with a reduced level of glycosaminoglycans in the skin comprising applying to the skin afflicted with such a condition a composition containing an effective amount of a mannose phosphate.

14. The method of claim 13 in which the condition is selected from the group consisting of dry skin, lines and wrinkles, and the symptoms of chrono- and photoaging.

17. The method of claim 13 in which the mannose phosphate is mannose-6-phosphate.

18. The method of claim 13 in which the effective amount is from about 0.01 to about 10% by weight of the total composition.

19. The method of claim 13 in which the effective amount is from about 0.01 to about 1% by weight of the total composition.

EVIDENCE APPENDIX

A. Fisher, et al., abstract,"Molecular mechanisms of photoaging in human skin in vivo and their prevention by all-trans retinoic acid", Photochemistry and Photobiology, February 1999.

B. Healthier living, online; "Ageing – the skin"; http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Ageing_the_skin?open; accessed no later than January 27, 2006.

Exhibits attached.

A

Molecular mechanisms of photoaging in human skin in vivo and their prevention by all-trans retinoic acid

Photochemistry and Photobiology, Feb 1999 by Fisher, Gary J, Talwar, Harvinder S, Lin, Jiayuh, Voorhees, John J

Gary J. Fisher*, Harvinder S. Talwar, Jiayuh Lin and John J. Voorhees

ABSTRACT

Solar UV radiation damages human skin, affecting skin tone and resiliency and leading to premature aging (photoaging), the symptoms of which include leathery texture, wrinkles, mottled pigmentation, laxity and sallowness. We propose that photoaging results largely from UV induction of matrix metalloproteinases (MMP) that degrade skin collagen. We find that pretreatment of human skin with all-trans retinoic acid (tRA) inhibits UV induction of MMP, suggesting that tRA can protect against UV-induced collagen destruction and may therefore be able to lessen the effects of photoaging. The tRA prevents UV-induced accumulation of c-Jun protein, which is required for MMP gene expression. Activation of c-Jun transcriptional activity requires N-terminal phosphorylation. The majority of c-Jun in human skin in vivo is Nterminal phosphorylated. Topically applied tRA does not inhibit N-terminal phosphorylation by UV-induced c-Jun kinase activity in human skin. The tRA likely acts to reduce UV induction of c-Jun protein by stimulating its breakdown through the ubiquitin-proteasome pathway.

B

http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Ageing_the_skin?open

Ageing - the skin

The skin is one of the first body parts to show age. While many of these age-related changes are inevitable, some can be reduced with healthy lifestyle choices and good skin care. Many people accept that changes to their skin are part of the normal ageing process. If, however, you want to try one or more of the anti-ageing treatments on offer, consult with an experienced cosmetic dermatologist and make sure you understand all the potential risks, complications and side effects of the treatment.

Skin layers explained

The uppermost layer of the skin is called the epidermis. This layer contains pigment-producing cells (melanocytes) that give skin its colour. New epidermal cells are born in the basal cell layer of the epidermis - the living layer of the epidermis. The stratum corneum, also known as the 'horny layer', is the outer layer of the epidermis. It contains keratin and is made up of dead cells. Cells of the epidermis start in the basal cell layer and then gradually rise to the surface, while older dead cells are sloughed off.

Beneath the epidermis is the dermis, which contains blood and lymph vessels, nerves, sweat glands and oil glands. Hair follicles are extensions of the epidermis into the dermis. The dermis is made up of networks of elastic fibres (elastin) for suppleness and dense fibres (collagen) for strength. Finally, a layer of fatty tissue lies below the skin and gives it structure.

The skin is one of the first body parts to show age and, while many of these age-related changes are inevitable, some can be reduced with sensible lifestyle choices and good skin care.

Signs of ageing

Some of the signs of ageing skin can include:

- **Thinning** - the basal cell layer of the epidermis slows its rate of cell production and thins the epidermis. The dermis may become thinner. Together, these changes mean skin is more likely to crepe and wrinkle.
- **Sagging** - older skin produces less elastin and collagen, which means it is more likely to sag and droop. Older skin is particularly vulnerable to the effects of gravity - for example, jowls along the jaw and bags under the eyes are simply skin that has yielded to gravity.
- **Wrinkles** - reduced elastin and collagen, and the thinning of skin, mean those 'high traffic' areas of the face (like the eyes and mouth) are especially prone to lines and wrinkles.
- **Age spots** - the remaining pigment cells (melanocytes) tend to increase in certain areas and cluster together, forming what's known as age or liver spots. Areas that

have been exposed to the sun, such as the backs of the hands, are particularly prone to age spots.

- **Dryness** - older skin has fewer sweat glands and oil glands. This can make the skin more prone to dryness-related conditions, such as roughness and itching.
- **Broken blood vessels** - blood vessels in older, thinner skin are more likely to break and bruise. They may also become permanently widened. This is commonly known as broken vessels.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings or decisions.